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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,957	11/13/2001	Hans Herweijer	Mirus.025.01	8989
25032	7590	02/16/2005	EXAMINER	
MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/992,957	HERWEIJER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Daniel M Sullivan	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-12 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/12/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 December 2004 has been entered.

Claims 1-12 and 25-27 were previously pending and under consideration. Claims 1 and 25 were amended and claim 8 was canceled in the 3 December Paper. Claims 1-7, 9-12 and 25-27 are pending and under consideration.

### ***Response to Amendment***

Rejection of claim 8 is rendered moot by the cancellation thereof.

### **Claim Objections**

Objection to claims 1 and 25 is withdrawn in view of the amendments thereto.

### **Claim Rejections - 35 USC § 112**

Rejection of claims 1-7 and 9-12 under 35 U.S.C. 112, first paragraph, as containing new matter is withdrawn in view of the amendments thereto.

### **Claim Rejections - 35 USC § 102**

Rejection of claims 25 and 27 under 35 U.S.C. 102(b) as being anticipated by either one of Liu *et al.* or Zhang *et al.* is withdrawn in view of the amendment of claim 25 such that the

Art Unit: 1636

method comprises the step of isolating antibodies or immune cells producing antibodies from the rodent.

Claims 1-6 and 9-12 stand rejected under 35 U.S.C. 102(b) as being anticipated by either one of Liu *et al.* or Zhang *et al.* for reasons of record and herein below in the response to arguments.

Claim Rejections - 35 USC § 103

Rejection of claim 26 under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* or Zhang *et al.* and further in view of Smyth-Templeton *et al.* is withdrawn in view of the amendment of claim 25 (*Id.*).

Claim 7 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* or Zhang *et al.* and further in view of Smyth-Templeton *et al.* for reasons of record and herein below in the response to arguments.

***Response to Arguments***

Claim Rejections - 35 USC § 102

Claims 1-6 and 9-12 stand rejected under 35 U.S.C. 102(b) as being anticipated by either one of Liu *et al.* or Zhang *et al.*

In response to the *prima facie* case of record, Applicant has amended claim 1 such that it now includes a part (e) which recites that the process steps set forth in parts (a)-(d) generate in

Art Unit: 1636

the mammal an immune response selected from immunization, vaccination, induction of a cellular immune response, induction of a humoral immune response, production of an antibody and production of immune cells that produce antibodies to the antigen.

Applicant argues that the claims are no longer anticipated by Liu *et al.* or Zhang *et al.* because there is no evidence in the publications of Liu *et al.* or Zhang *et al.* to indicate that it was known to the m at the time of publication that it was possible to generate an immune response to an expressed antigen following injection of DNA into the tail vein of a mouse.

This argument has been fully considered but is not deemed persuasive. The amended claim merely recites outcomes, which, absent evidence to the contrary, are presumed to be inherent to the method disclosed in the art. The art teaches a method that anticipates the method steps set forth in parts (a)-(d) of the claim; therefore, the outcome recited in part (e) must be inherent to the method unless the art is not enabling for that outcome. Although Applicant argues that Liu *et al.* and Zhang *et al.* provide no evidence that they were aware of an immune response resulting from their method, Applicant is reminded that, as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999). MPEP 2131.01. As stated in the final Office Action, “[a]lthough Liu *et al.* does not explicitly teach inducing an immune response, Liu *et al.* teaches expression of luciferase in various organs and tissues of mice, which is demonstrated in Example 5 of the instant application to elicit an antibody immune response. The specification teaches that the antibody response obtained by the method, “is not surprising given the large amount of antigen that is produced”

Art Unit: 1636

(page 41, line 20-21).” Thus, the extrinsic evidence supports the inherency of some immune response within the scope of the instant claim elicited by the method of Liu *et al.* and Zhang *et al.*

Applicant also cites art that allegedly evidences a suppressed immune responsiveness of the liver as compared with other tissues. However, while the art does suggest that expression of antigen in liver alone might lead to tolerance rather than an immunization against the antigen, the art does not assess immune responses to systemically delivered plasmid encoded antigen as provided in the method of Liu *et al.* and Zhang *et al.* In contrast, the instant application teaches that such systemic administration does, in fact, lead to an immune response. Finally, although Applicant argues that the statement from the specification cited in the Office Action “does not constitute an obvious expectation of the initial result”, the findings provided in the example support the inherency of the immune response regardless of whether one would, *a priori*, expect the result.

Applicant’s arguments have been fully considered but are not deemed persuasive either individually or as a whole, therefore, the claims stand rejected under 35 USC §102(b) as being anticipated by either one of Liu *et al.* or Zhang *et al.*

#### Claim Rejections - 35 USC § 103

Claim 7 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* or Zhang *et al.* and further in view of Smyth-Templeton *et al.*

Applicant’s position is that, because Liu *et al.* and Zhang *et al.* do not disclose the method of claim 1, the method of claim 7 would not be obvious to one of ordinary skill in the art.

Art Unit: 1636

This argument has been fully considered but is not deemed persuasive because, for the reasons stated herein above, the method of claim 1 is anticipated by the teachings of Liu *et al.* and Zhang *et al.* and, therefore, the method of claim 7 as a whole would be obvious to one of ordinary skill in the art for the reasons stated in the Final Office Action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by either one of Böhm *et al.* (1998) *Vaccine* 16:949-954 or Hurpin *et al.* (1998) *Vaccine* 16:208-215 (made of record in the IDS filed 12 January 2005).

Hurpin *et al.* teaches a method of generating antibodies specific to an antigen (*i.e.*, p53) comprising providing a nucleic acid encoding said antigen (*i.e.*, a canary pox vector (ALVAC) comprising the nucleic acid) and injecting the nucleic acid into the tail vein of a rodent (see especially the first full paragraph in the right column on page 209 and the first full paragraph in the right column on page 210). Hurpin *et al.* further teaches that the ALVAC vector provides expression in the liver (see especially the second full paragraph on page 210 and Table 1) and assays for anti-p53 antibodies in the immunized mice, which would include the step of isolating said antibodies from said mouse. Therefore, the method of Hurpin *et al.* comprises each of the process steps of the instant claim 25 and is practiced with a mouse according to claim 27.

Art Unit: 1636

Furthermore, the canary pox vector comprises the vector nucleic acid complexed with viral proteins, which viral proteins are polymers according to the limitations of claim 26.

Böhm *et al.* teaches injection of a plasmid vector encoding at least one antigenic determinant of HBsAg into the tail vein of mice (section bridging pages 949-950 and the second paragraph in the right column on page 950). In the paragraph bridging pages 952-953, Böhm *et al.* teaches that at least one of the mice developed a high specific serum antibody titer against HBsAg. Absent evidence to the contrary, and in view of the teaching of Böhm *et al.* implying that i.v. DNA injection leads to expression in liver (paragraph bridging the left and right columns on page 953, the sentence beginning at line 10), the skilled artisan would understand that the tail vein injections deliver the nucleic acid to a liver cell wherein the antigen is expressed. Further, the method of Böhm *et al.* includes isolating antibodies or immune cells producing said antibodies from the immunized mice (see especially the first paragraph on page 951). Therefore, the method of Böhm *et al.* comprises each of the limitations of the instant claims 25-27).

The method of Hurpin *et al.* or Böhm *et al.* is the same as the method of the instant claims 25-27; therefore, the claims are anticipated by the art and properly rejected under 35 USC §102(b).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.




Art Unit: 1636

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER